REMARKS

Claims 1-29 are pending. Claims 1,5,6, 13-18, 22-24, 28 and 29 have been amended. Claims 10,12,21, 25-27 have been cancelled. No claims have been withdrawn.

Support for the amendment to claims 1 and 12 requiring the shell to have an upper wall having an upper surface having a dry coefficient of friction against bone of at least 0.5 is found at page 4, line 9 of the as-filed specification.

Support for the amendment to claim 1 requiring a one piece shell is found in FIGS. 2b, 2c, 3b and 4.

Before addressing the substantive rejections, it is helpful to review the present invention, the present invention relates to a prosthetic intervertebral disc comprising:

a) a central core material having an upper surface, a lower surface and a sidewall therebetween, and

b) a non-resorbable one piece outer shell having an inner surface surrounding the central core and contacting the upper surface, the lower surface and the sidewall of the core,

wherein the outer shell has an upper wall having an upper surface having a dry coefficient of friction against bone of at least 0.5.

Applicants invention relates to the use of a single shell material that surrounds the core and has a high coefficient of friction in order to maintain stability.

As noted in the as-filed specification at page 2, lines 5-10, and 29-31, the conventional discs were characterized by having one material for the sidewall and another material for the endplate:

> Although the recognition in the Lee device of the need to mimic both the nucleus pulposus and annulus fibrosus components has its advantages, the provision in the Lee device of prosthetic endplates is problematic because it is known that the shear forces associated with natural vertebral

> movement will cause large shear stresses at the interfaces between the prosthetic endplates (on one hand) and the prosthetic nucleus pulposus and annulus fibrosus components (on the other hand)...
> Although Parsons improves upon Lee by providing for a higher stiffness in the annulus fibrosus component, Parsons nonetheless retains the problematic endplate components of Lee.

By using a single material for surrounding the core, Applicant avoids the large shear stresses at the interfaces between the prosthetic endplates (on one hand) and the annulus fibrosus components (on the other hand).

The conventional art was also characterized by a reliance upon bony ingrowth for implant stability. See page 3, line 29 to page 4, line 2.

By using a single material having an outer surface having a high coefficient of friction, the present invention need not rely upon bony ingrowth or spikes for stability.

Claims 10 and 23 are objected to in that claim 10 has the phrase "(High COF)", and claim 23 has the word "silicon".

Applicant has deleted claim 10. In claim 23, Applicant has replaced "silicon" with "silicone".

Claim 24 stands rejected under 35 USC 112, first paragraph as failing to comply with the enablement requirement.

The Examiner took the position that since the core simulates the behaviour of the nucleus pulposus, it can not be harder than the sidewall of the outer shell.

Claim 24 has been amended so that the central core has a lower hardness and the sidewall of the outer shell has a higher hardness.

Claims 5, 6 and 25 stand rejected under 35 USC 112, second paragraph for indefiniteness.

Applicants have amended claim 5 to make the claim even more clear that the thickness of the upper wall is lower than the thickness of the side wall.

In respect of claim 25, this claim has been cancelled.

Claims 1,2,5-8 stand rejected as anticipated by US Patent No. 5545229 (Parsons).

Applicant has noted that Parsons teaches a disc having separate endplate and annulus fibrosus components. See e.g., FIG. 3 of Parsons. Accordingly, Parsons does not teach a one-piece outer shell contacting the upper surface, the lower surface and the sidewall of the core.

Accordingly, the present rejection should be withdrawn.

Claims 1,2,5-6, and 11 stand rejected as anticipated by US Published Patent Application No. 2002/0082701 (Zdeblick).

Although Zdeblick may teach a unitary shell (see FIG. 24), Zedblick does not teach that the outer surface of this shell should have a high friction coefficient to maintain implant stability.

Claims 3-4, 10-17 and 20-29 stand rejected under 35 USC 103 as unpatentable in view of US Patent No. 5545229 (Parsons).

As noted above, Parsons does not teach a unitary shell and so can not render these claims, which depend from claim 1, unpatentable. Further, Parson appears to rely heavily upon the endplate-annulus design for a shell, and provides different criteria for these two components. Therefore, the skilled artisan would not be motivated to replace the two component shell of Parsons with a unitary design.

Claim 9 stands rejected under 35 USC 103 as unpatentable in view of US Patent No. 5545229 (Parsons) in view of Higham (US 2004/0054413).

As noted above, Parsons does not teach a unitary shell and so can not render this claim, which depend from claim 1, unpatentable. Higham is cited merely for its teaching

of a radiopaque implant and so does not cure the deficieincies of Parsons. Accordingly, this rejection should be withdrawn.

Claims 3-4, 10, 14-20 stand rejected under 35 USC 103 as unpatentable in view of Zdeblick.

As noted above, Zdeblick does not teach a shell having a high friction coefficient and so can not render these claims, which depend from claim 1, unpatentable.

Moreover, in that Zdeblick further teaches that its shell is housed within upper and lower endplates (See FIG. 16), the skilled artisan would not be motivated to modify Zdeblick to provide a high friction coefficient upon the outer shell surface, as implant stability is already provided by the Zdwblick's endplates.

Claim 9 stands rejected under 35 USC 103 as unpatentable in view of Zdeblick in view of Higham.

As noted above, Zdeblick does not teach a shell having a high friction coefficient and so can not render these claims, which depend from claim 1, unpatentable. Higham is cited merely for its teaching of a radiopaque implant and so does not cure the deficieincies of Zdeblick. Accordingly, this rejection should be withdrawn.

In addition, please provide any extensions of time which may be necessary and charge any fees which may be due to Deposit Account No. 10-0750, but do not include any payment of issue fees.

Should there be any remaining or further questions, the Examiner is requested to place contact the undersigned directly.

Respectfully submitted,

Thomas M. DiMauro
Attorney for Applicants
Reg. No. 35,490
Johnson & Johnson
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933
(508) 880-8401